Food Additives and Contaminents Committee

Report on the Leaching of Substances from Packaging Materials into Food

CORRECTIONS

Page 3 — Contents page – Sub heading "Evidence of Lazard" should read "Evidence of Ha

The word "evidence" underneath the entry "An inherent risk" should be deleted.

Page 7 Para 15 — heading "Evidence of Lazard" should read "Evidence of Hazard".

Page 20 — Para 4 line 2 the word "chacter" should read "character".

Ministry of Agriculture, Fisheries and Food

May 1970

LONDON: HER MAJESTY'S STATIONERY OFFICE

MINISTRY OF
AGRICULTURE, FISHERIES AND FOOD

FOOD ADDITIVES AND CONTAMINANTS COMMITTEE REPORT ON THE LEACHING OF SUBSTANCES FROM PACKAGING MATERIALS INTO FOOD

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1970

Price 2s. 3d. [11p] net

FOOD ADDITIVES AND CONTAMINANTS COMMITTEE

The terms of reference of the Food Additives and Contaminants Committee are:

"To advise the Minister of Agriculture, Fisheries and Food, the Secretary of State for Scotland, the Secretary of State for Social Services, and as respects Northern Ireland, the Secretary of State for the Home Department, on matters referred to them by Ministers, in relation to food contaminants, additives and similar substances which are or may be present in food, or used in its preparation, with particular reference to the excercise of powers conferred on Ministers by Sections 4, 5 and 7 of the Food and Drugs Act, 1955 and the corresponding provisions in enactments relating to Scotland and Northern Ireland."

The members of the Food Additives and Contaminants Committee during the review were:

Professor R. A. MORTON, D.Sc., Sc.D., Ph.D., F.R.S., F.R.I.C. (*Chairman*) (until November 1968)

R. DE GIACOMI, ESQ., F.R.I.C. (until November 1968).

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At the time of completion of the Report (March 1969) the following were members:

Professor B. C. L. WEEDON, D.Sc., Ph.D., F.R.I.C. (*Chairman*) (from December 1968)

Professor F. AYLWARD, D.Sc., Ph.D., F.R.I.C. (from December 1968)

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FOOD ADDITIVES AND CONTAMINANTS COMMITTEE

THE LEACHING OF SUBSTANCES FROM PACKAGING MATERIALS INTO FOOD

Contents — *Paragraph numbers*

SCOPE OF THE ENQUIRY

1. We were asked to examine the question of the migration of chemicals to food from containers, packaging material and printing inks. Our enquiry was to include the migration of any chemicals from can linings where such linings were not of elemental metal, but contamination arising from the corrosion of the interior surfaces of metal cans was omitted.

2. The significance of the contamination of food from these metals has been the subject of previous detailed reports[1] and lead in food is now the subject of statutory control.[2] However, we have given consideration to the possibility of the migration to food of heavy metals such as cadmium from packaging materials and of migrants from lacquers used to line metallic containers, together with possible migratory substances from all other forms of man-made packaging materials used to wrap or contain food. We have taken the view that the component parts of a packaging material are all liable to contribute migratory substances to a food with which they are in immediate contact.

PRESENT LEGISLATIVE POSITION

3. At present, there are no regulations which specifically control the composition of packaging materials or the migration of substances from packaging material to food. Regulation 10 of the Food Hygiene (General) Regulations, 1960 and Regulation 10 of the Food Hygiene (Market, Stalls and Delivery Vehicles) Regulations, 1966 lay down that 'a person who engages in the handling of food shall not while so engaged—

(a) carry any food in a vehicle or container together with any article from which there is a risk of contamination of the food, or with any live animal or live poultry, without taking all such precautions as are reasonably practicable to avoid risk of contamination, and in particular (without prejudice to the generality of the foregoing) shall not allow any live animal or live poultry to come into contact with food; or

(b) use for wrapping or containing any open food any paper or other wrapping material or container which is not clean or which is liable to contaminate[3] the food, and shall not allow any printed material, other than printed material designed exclusively for wrapping or containing food, to come into contact with any food other than uncooked vegetables or unskinned rabbits or hares, or unplucked game or poultry.'

The migration of chemicals from packaging material might be subject to action under Section 1 or Section 2 of the Food and Drugs Act, 1955 as an addition of a substance so as to render the food injurious to health or as rendering the food not of the nature, substance or quality demanded. Migration might also bring about the presence in food of substances forbidden by regulations made under the Food and Drugs Act. There is a special provision in the Preservatives in Food Regulations 1962 for the presence in food of not more than 5 parts per million (ppm) of formaldehyde derived from any wet strength wrapping containing any resin based on formaldehyde or from any plastic food container or utensil manufactured from any resin of which formaldehyde is a condensing component.

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[1] Food Standards Committee Report on Lead 1954: H.M.S.O., Food Standards Committee Report on Tin in Canned Fish, Ministry of Agriculture, Fisheries and Food, 1952.

[2] Lead in Food Regulations, 1961 S.I. 1961 No. 1931.

[3] 'Contamination' includes contamination by odour.

4. We have taken legal advice and have been informed that it would be possible for Ministers to make regulations to control the composition of packaging materials or to require or prohibit certain substances to be used in packaging material, provided that they consider it to be expedient for the protection of public health, under Section 13(1) of the Food and Drugs Act, 1955 and the corresponding Scottish and Northern Ireland provisions. Section 13(1) reads as follows:—

"The Ministers may make such regulations as appear to them to be expedient for securing the observance of sanitary and cleanly conditions and practices in connection with—

(a) the sale of food for human consumption, or

(b) the importation, preparation, transport, storage, packaging, wrapping, exposure for sale, service or delivery of food intended for sale or sold for human consumption,

or otherwise for the protection of the public health in connection with the matters aforesaid."

CONDUCT OF THE ENQUIRY

5. A great number of written representations were submitted by the packaging and food industries and also by enforcement authorities in response to the Press Notice which announced our enquiry. During the review we asked for and received further written evidence and we also took oral evidence from the British Plastics Federation.

6. Before deciding what our recommendations should be, we set out preliminary conclusions and invited the main interested parties to express their views on them. All those invited to do so submitted further written evidence. We then took oral evidence from representatives of the plastics and paper trades and from the British Industrial Biological Research Association.

7. We wish to express our appreciation of the co-operation of all those concerned. The list of those who made written representations or gave oral evidence is given at Appendix I.

CONTROL SYSTEMS IN OTHER COUNTRIES

8. During the review we considered the various systems of statutory and voluntary control at present in force in other countries and in particular in the United States of America, France, Federal Republic of Germany, Italy, the Netherlands and Switzerland. We were also informed of progress being made in international discussions on the control of packaging materials in the Council of Europe (Partial Agreement) and in the Codex Alimentarius Commission.

9. There are significant differences in the control systems operated by other countries and in the resources allocated to them. Some are virtually licensing systems for each package which involves scrutiny of every formulation, individual testing arrangements and very detailed authorisations; such control systems take up a lot of administrative, scientific and industrial resources. Other systems are lists of permitted ingredients in plastic packaging materials with or without specified conditions but which leave some room for manoeuvre; these systems are relatively less expensive to operate. All control systems use food-simulating solvents in one way or another but the detailed rules about methods and the individual solvent procedures are different. It would be to the advantage of both the food and the packaging trades if the same control system could apply

in all major countries but because of the nature of the problem progress towards harmonisation is bound to be slow. The task of devising effective control measures which do not take up a disproportionate and unjustified amount of governmental, scientific and trade resources has not yet, in our view, been solved anywhere.

ASSESSMENT OF THE PROBLEM

The need for control

10. Food is packaged to preserve quality and freshness, to make the product more attractive and to make distribution easier. Packaging can also provide an effective barrier against the entry of dirt and contaminants such as micro-organisms and thereby greatly reduce the incidence of hazard from these sources. On the other hand, the packaging material or the container can itself foster mould growth and it is now generally accepted that it can include chemicals which can and do migrate into the food. Wrapping materials, particularly paper, have been used for many years to package food and it has been contended that this affords presumptive evidence of safety-in-use. We could not accept this presumption for reasons given below (paragraph 15 *et seq*). Even with the simplest wrapping material, care has always been necessary to avoid adverse effects on the taste, odour and appearance of the wrapped food. With paper, and also with cardboard, there has always been the problem that the re-use of certain types ot waste paper might prove deleterious.

11. The number of packaging materials is now very large, their individual characteristics differ widely and many substances are used in manufacture of individual types; new ingredients, new formulations and new uses are introduced frequently. Technological change has become of special significance with the development of plastics for the formulation of which large numbers of chemicals, many of them new, are used in complex manufacturing processes, The current demand for plastic packaging makes it necessary for plastic manufacturers to have at their disposal for packaging materials as a whole (i.e. for food and non-food wrapping) from 5,000 to 15,000 different chemical compounds from which to make a choice to produce formulations for particular uses. Many packaging materials do not, of course, involve immediate contact with food. The fabrication of packaging materials to suit specific kinds of food and, at the same time, to meet specific technological needs calls for a balance between technological advantage for the manufacturer with indirect benefit for the consumer and the problem of ensuring that a given product is not injurious to health and that it does not adversely affect the taste, odour or appearance of the wrapped food.

12. Packaging materials present a hazard to health:

(a) if the surface layer in contact with food
  (i) contains toxic substances which can be transferred to food;
  (ii) contains non-toxic substances which can react with food to produce toxic substances;
  (iii) favours the multiplication of micro-organisms;

(b) if a 'liner' or the surface layer of a laminate fails to act as a barrier to unwanted material; and

(c) if the environmental conditions favour migration and the migrants are harmful by any one of several recognised criteria.

13. Because of the multiplicity of wrapping materials and of their ingredients the risk with an individual type of packaging may often be small and the risk of the cumulative ingestion of any one migrant may be considerably reduced.

14. Migrants from packaging materials into food can cause "off-flavours"; in fatty foods the effect of migration may not necessarily be revealed by an off-odour although it might cause nausea. Physical conditions can favour migration. Where contamination of foods by volatilisation is a possibility, the extent, duration and temperature of contact are major factors. With any kind of container for liquids, diffusion processes increase the extent of possible migration because of the constantly renewed contact. In general, fatty foods are the most susceptible to contamination by migrants. Film or paper used to wrap chocolate and sugar confectionery adheres closely and the contact area per unit weight is high for small portions. However, when a dry commodity like sugar, salt or tea is packaged in paper bags or cartons the material is subject to abrasion rather than leaching.

Evidence of Hazard

15. Evidence of injury to human health caused by the migration to food of chemical substances from packaging materials is virtually non-existent, doubtless because the necessary investigations are difficult and would only be undertaken on well-founded suspicions. The damage to human tissues by exposure to a particular agent can pass unnoticed or remain dormant for many years and only when overt injury to health becomes evident in many people at the same time can cause be related to effect. Moreover, risks to health may vary from person to person and from substance to substance.

16. In the light of present knowledge, it cannot be said with any degree of certainty that migration from packaging materials into food, whether by leaching or by volatilisation, presents no risk to health. There is a continuing need to establish what the risk is, to assess potential hazard in the light of an expanding technology, and to eliminate the hazard to the maximum extent that circumstances and resources permit. In the absence of regulations, industry has been guided in some instances by the results of systems of control in other countries. In other instances, notably with plastics, industry has developed voluntarily a code of practice which seeks to relate the toxicity of ingredients to possible safety-in-use of packaging formulations. More recently the British Plastics Federation has joined with the British Industrial Biological Research Association in drawing up a joint code of practice which has the advantage that the assessment of toxicity is in the hands of an independent expert body.

Comparison with control of food additives

17. The problems associated with migration from packaging materials are incredibly complex and they present difficulties not encountered in the field of direct food additives. With food additives, composition and purity can be prescribed and safety-in-use can be related to toxicological evaluation in both test animals and humans. Levels of use of food additives can, where necessary, be limited to acceptable daily intake figures calculated from evaluation of effects on whole animals and where appropriate, on the "target organs" of such animals. Moreover, adequate safety factors can be applied to such intake figures in order to increase the available margin of safety, particularly if such additives are permitted in foods generally rather than restricted to specific classes of foods.

18. With contaminants migrating from packaging materials, no such direct control or evaluation of safety-in-use is practicable. Control with regard to both

exposure and quantity is imprecise and the recognition of the incidence of injury to health depends on interpretation of medical statistics collected over long periods of time. Migrants from packaging materials are examples of a type of indirect additive to food wherein the potential health hazard is ever-present, and where hazard may tend to increase with technological advance by industry and with an ever increasing complexity of demand.

An inherent risk

19. It cannot be denied that there is an inherent risk in the use of packaging materials for wrapping food. This risk must be set against the undoubted benefits. In our judgment, any system of control for packaging materials for use with food should therefore be no more exacting than the situation demands. It should neither erect a serious barrier to trade or to innovation nor should it call for too great a share of the available scientific resources; in particular, it should not take up a disproportionate amount of the scarce expert resources for testing and for the assessment of the safety-in-use of food additives. This aim is easier to enunciate than to achieve. The problem has not yet been satisfactorily solved anywhere. The technological goals of packaging are numerous, varied and constantly changing. The evidence submitted indicated that the range of properties needed in the many different types of paper, film or plastic contact wrappings and containers can only be attained if manufacturers have at their disposal a large number of chemical substances for incorporation, as appropriate, in the mixture of products needed to obtain the desired characteristics in each finished packaging material. Migration can and does occur, and we have been told—and we accept—that some degree of migration is inevitable. The tendency to migrate can be affected by minor changes in formulation of a product or in manufacturing procedure which are outside the control of suppliers of raw materials. For this and other reasons, suppliers and manufacturers have insisted that control, if it is to be practicable, must be effected by means of a permitted list of ingredients of packaging materials. In our view, however, the safety-in-use of packaging materials is best achieved by a system of control which is based to the maximum possible extent on the identification and regulation of the substances that migrate into food since it is these substances—and not necessarily the ingredients in the package—that constitute the sources of any risk to the consumer of the food.

20. We have not been able in the present state of knowledge to determine the extent of any risk to the consumer. Although industry has done some work on the migration of substances and has provided information to the Committee, there is not sufficient factual information available about the extent of, or the nature of, the migration from packaging materials into food. We consider it essential that much more factual information should be obtained as soon as practicable in order that the risk to the consumer can be properly assessed and so as to enable the appropriate control system to be developed. Meanwhile our recommendations are designed as a means of introducing a system of control which would offer some safeguards for the consumer while stimulating industry to do the work we consider necessary.

Co-operation by industry

21. A fundamental safeguard is the willingness of industry to act responsibly. Industry has shown active concern in the problem of packaging materials as illiustrated by the operation of such schemes as that devised by the British Plastics Federation's Toxicity Testing Sub-Committee. In the case of plastic packaging materials, the Toxicity Testing Sub-Committee reviewed the problems associated with the contamination of foodstuffs by packaging migrants and proposed various practical tests for potential toxicity. More recently this same Federation has

extended its services to member companies to include a scrutiny of the available toxicological evidence on ingredients of new packaging formulations by toxicologists of the British Industrial Biological Research Association (BIBRA) who have much experience in the evaluation of the safety-in-use of food additives.

Use of packaging materials for specified purposes

22. Important steps towards safety-in-use would be to ensure that all packaging materials were used only for designated purposes and that appropriate specifications were laid down for products for particular purposes. This would involve selection and identification of packaging products on a statutory or a voluntary basis and education of food manufacturers, wholesalers, retailers and the food-consuming public. Many wrappings and containers are designed and intended to be disposed of after a single use. Some people already find this concept difficult to accept and there is a need to familiarise the general public with the idea. Today, the balance of advantage, for both commercial and user interests is often markedly in favour of disposable containers. Specifications might therefore, where appropriate, be orientated towards "once-only" usage. Disposable containers for beer, ice-cream and soft drinks and, of course, milk cartons might usefully be in this category.

23. Attractive materials are often used to pack many non-food products and anxiety has been expressed that in the home some of these might be re-used for food. Although the Food and Drugs Act does not extend to usage in the home, we think industry should consider whether packaging should be marked "suitable for food use" in appropriate cases.

24. Some food wrapping materials are designed for miscellaneous end-uses, but many are designed for a particular purpose (e.g. the "boil in the bag" plastics). Specific requirements for wrappers or containers might, on occasion, need to be made explicit; for example, there are several types of greaseproof paper. Fresh meat and fish may first be placed in contact with a suitable paper and then perhaps wrapped again by the retailer in another type of paper. Clearly the primary wrapper, in contact with the food, warrants a stricter specification than the other wrapping material and both types should not be confused by users. With multiple layer packaging, the liner, or contact layer of a laminate, might usefully be tested both as a source of migrants and as a barrier, particularly if the projected end-use was for wrapping fatty foods. With dry foods wrapped in paper or cardboard containers, any contamination would arise from abrasion. Cellulosic products are of major importance in food packaging and the many different requirements in relation to the varied usage of such materials ought to be made explicit in terms of specifications tied to end-usage.

Printing inks

25. Contact between food and printed material is subject to control by the hygiene regulations (see paragraph 3 above). It is in fact comparatively rare for "print" (derived from printing inks) to be in direct contact with food. In addition to the possibility of direct migration, attention must be drawn to the possibility that certain volatile organic substances are produed as certain types of ink dry. Unless therefore the printed paper or board is allowed to dry for the appropriate time, the ketones, aldehydes and esters produced may well volatilise and be absorbed by the food when it is overwrapped by cellulosic film. The result could then be to produce off-flavours in the food.

Paper and cardboard

26. From the standpoint of safety-in-use, the advantages of high quality raw

materials are clear. Our attention has been drawn to the significant part played by waste recovery in the paper manufacturing process and to the fact that there is a risk of entry into refabricated products of inorganic substances or of organic material arising from inks, pigments, dyes and preservatives used previously. What is not known, however, is whether such risks are of quantitative significance. Where paper or cardboard is intended for direct contact with food, any risk from waste-recovery residues could be eliminated by using only virgin wood pulp. Any extra costs which might arise thereby would have to be compared with the cost of any additional analytical control which might be considered necessary.

Glass

27. It has also been brought to our attention that extractability from glass may, on occasion, compare unfavourably with extractability from selected plastics. We have found no evidence of toxicity from this source, but consider that systematic extraction tests on glass food containers are essential in order that the risk, if any, can be assessed. Containers for milk are of special importance since (a) milk is consumed daily in large amounts, particularly by children, (b) as a liquid containing an emulsion of fat it is an effective extractant, and (c) glass containers are re-used a number of times, with intervening treatments by sterilising chemicals and processes. In this context, it must also be remembered that the use of disposable containers for all dairy products is on the increase and that there are significant benefits arising from strict specifications for all containers for these staple items of the diet.

Plastics

28. Packaging materials made from plastics and flexible packaging are complex mixtures and the problem posed by their use is of much greater scale than for packaging materials made from other substances. We have prepared a layman's note as Appendix IV on some of the points of particular interest in connection with plastics packaging materials. The plastics packaging industry has had to reconcile the demands of technical progress in highly competitive circumstances with the need to provide a safe and satisfactory packaging material for food. The fact that the package can sometimes contaminate food by affecting odour, taste or appearance has imposed some restriction on the composition of plastics packaging materials, but we consider that more attention should be given to the need to reduce the area of risk by restricting the number of substances used in a formulation to those which are known to be safe or are thought, on the balance of probabilities, to be safe. The plastics industry has spent a considerable amount of time and money on a voluntary system of control under the aegis of the British Plastics Federation. This system, together with the statutory and voluntary controls exercised in other countries have certainly reduced the area of risk from the migration of substances from the package into food; this risk is intrinsically relatively small.

Assessment of risk and the factor of scarce resources

29. The risk to the consumer of the food arises from the presence in the food of a substance that should not be there. In the United Kingdom we have a system of permitted lists for the main classes of food additive and the substances on these lists are now scrutinised in accordance with the procedure described in the Memorandum on Procedure for Submissions on Food Additives and on Methods of Toxicity Testing. (H.M.S.O. 1965).

30. Testing of chemical substances for safety-in-use in food, as required by the Memorandum, is usually a lengthy and costly business. Expert resources are limited and are already fully engaged on the evaluation of food additives and

important related matters. In the circumstances, it is neither prudent nor realistic to consider imposing a system based on testing all ingredients of packaging materials because of the possibility that they might migrate into food. In any case, we consider that the risk derives from what comes out of the wrapper into the food and not from what is put into the making of the wrapper. There is not enough incontrovertible information about the substances that actually migrate or even about those which are believed to migrate because they can be extracted by tests with food simulating solvents. We think that information about migration should be obtained over a reasonable period of time for all packaging materials whether plastics, paper, glass or other substances. We would hope that one effect of such a requirement would be to stimulate a move towards the use of fewer ingredients.

TACKLING THE PROBLEM

Methods of control

31. On the assumption that the evaluation of risk to the consumer can be shown to justify special control to supplement the general provisions of the Food and Drugs Act, we considered various methods. We first considered whether control could be based on analytical testing of the food itself which would have the advantage of dealing with the substances which actually migrated from the packaging material. This sort of control would fall naturally into line with the on that has been developed for food additives and which is based on the statutory permitted lists of food additives that may be present in food.

32. Control on the food itself would however call for very sensitive analytical techniques for the detection, identification and, where appropriate, the measurement of very small amounts of one or more of a large number of possible migrants in the presence of the components of the food which would usually be present in larger amounts. Most foods are in any case complex mixtures. Some of the difficulties might be reduced if the enforcement authority knew the composition of the packaging material but this knowledge would not necessarily be available as part of the system of control.

33. We do not therefore consider that, at the present time or in the immediate future, it is practicable to base a system of control on analysis of the food. A substitute must therefore be found. The one adopted by most countries is the use of food simulating solvents.

The use of food-simulating solvents

34. If the potential migration is to be measured in a meaningful way, it is necessary for practical purposes, to represent a range of foods with which wrapping materials might come in contact. The food-simulating solvent is designed to do this. The description "food-simulating solvent" has been very widely used and we feel it should be retained despite the fact that it is often misunderstood. The choice of solvents depends largely on convenience, but the systems we would propose as suitable for the United Kingdom do not differ markedly from those in use in the United States and on the continent of Europe.It would clearly be desirable if all countries could adopt the same solvent systems, the same conditions of application, and present the results of such tests in the same way.

35. In deciding on the most appropriate solvent system, it is necessary to consider among other things, the various types of food, their degree of acidity or alkalinity (pH), packaged life and temperature during manufacture and storage.

Accelerated tests of extractability under severe experimental conditions may, in certain cases, be calibrated by the separate determination of the effect of temperature and the time of extraction, In order to achieve reproducibilty, the extraction conditions must be precisely defined and the results presented in a uniform manner. The results of extraction tests must be interpreted with caution; many results have shown far from perfect correlation with results of actual migration provided by methods involving the use of radioactive tracers. Nevertheless, a system of extraction using simple solvent systems and under carefully controlled conditions offers the most practical means of investigation and control. We have, in our deliberations concerning all aspects of leaching from packaging materials, taken account of the current practices in other countries although these differ widely in detail. In our selection of solvents we have done our best to harmonise so far as possible with the legislation of countries to which we know United Kingdom manufactured packaging materials are exported. At the same time, we have deliberately avoided a complex and multifarious system of different solvent extraction methods.

36. The solvent systems which we consider suitable and details of which are given in Appendix II are simple extraction media used in accelerated tests for potential migration. They simulate food to the extent that they reproduce approximately the acidity and the lipophilic or hydrophilic characteristics of the kinds of food to be packaged. We would consider the acceptance of data based on any other reasonable solvent systems. We recognise that the extraction conditions may not be as appropriate to laminated materials as to unlaminated foils: the same solvents, however, could also be used in cell extraction tests of the type described by the U.S. Food and Drug Administration. (Official Methods of Analysis of the Association of Official Agricultural Chemists, 10th Edition, 1965, sections 7.034-7.039). As a general principle, analytical control should be in respect of potential migration (i.e. extractability) and any tolerance limits should be defined in terms of standard extraction tests. Tolerance limits would be set either generally or in particular cases taking into account all the relevant considerations, including any evidence concerning the extent to which extractability exceeds the probable migration into actual foods under normal conditions.

37. In considering the setting of tolerance limits and other aspects of control it would be necessary to consider separately the different types of packaging materials which can conveniently be grouped under the following headings:

(a) paper and paper products;
(b) other flexible wrapping materials including plastics, foils, cellulose;
(c) glass;
(d) can liners (other than metallic); and
(e) miscellaneous.

Control by permitted list—ingredients or migrants

38. Whilst most people agree in principle that control need only be directed to substances that migrate, the idea of control by a permitted list of migrants does not command support, particularly from industry. It is contended that the manufacturer must know what he can put into a product and that control of migrants would transfer responsibility to packaging fabricators which would be unworkable or at least very difficult in practice. We were told that determination of migrants would entail examination of each and every packaging material (including examination after each and every change in manufacturing practice). It was also

suggested that an ingredient might migrate differently in different formulations and under different conditions of use and that a new method of analysis might convert what had appeared to be a non-migrant into a migrant overnight. It was also pointed out that if the migrant could not be identified and synthesised it would probably not be possible to collect enough for toxicity testing.

39. These are compelling practical reasons against a statutory control of migrants. On the other hand, these same points add strong emphasis to the view that control by permitted ingredients in the packaging material though more convenient and more practicable would not be dealing completely with the problem.

40. Control by ingredients would enable the manufacturer to know what he was allowed to use. However, a permitted list of ingredients would be very difficult, if not impossible, to enforce effectively by analysis and it is doubtful whether resources for inspection would ever be such as to justify more than a spot check from time to time. Moreover enforcement by inspection could not be extended to imported packaging material.

41. Control by permitted ingredients is used in some countries although methods may differ. In our view, it would not be satisfactory to have one general comprehensive list for all materials but several overlapping lists could be drawn up to contain chemical substances for stated kinds of product, e.g. types of paper, board, and plastic. End-use of the packaging material would have to be considered as for example, a plasticiser suitable for products in contact with aqueous food might not be suitable for foods containing much fat or for alcoholic beverages. A low molecular weight polymer might permit migration when a high molecular weight polymer would not.

42. For all these reasons, we have concluded that any permitted list of ingredients must be based to the maximum possible degree on information about migration under specified conditions. Our recommended list of solvents is intended to be a means of achieving this end. Co-operation of the packaging industry will be essential if a practicable method of control is to be devised in detail and, thereafter, if it is to work effectively.

Safety criteria for inclusion on the permitted list

43. Before considering how best to evolve a system of control by permitted lists of ingredients, it is appropriate to consider whether. for the practical reasons referred to in paragraph 30, the criteria for testing for or assessing the safety-in-use can be relaxed in the case of packaging materials. We think they can and that it is essential that they should be. We consider that as the area of hazard to health is small, it would be sensible to take and accept the risk that follows from limited testing. To do otherwise would overload testing resources which are scarce and which should not be diverted from tasks of greater priority and importance. The implications of relaxing the usual rules and the way in which this might be done will have to be considered after examination of any list of substances that may be submitted for inclusion in a permitted list. At that stage we and the Pharmacology Sub-Committee would be able to examine the whole of the prolem and make a better assessment of risks and benefits.

44. Subject to this further examination we consider that the approach put forward by Dr. Frawley (a summary of which is given in Appendix III), and which is being closely examined in the United States of America, provides a useful practical basis for action. Dr. Frawley has shown that ingredients used in a packaging material in very small quantities, i.e. less than 0·2% by weight are unlikely to re-

present a significant hazard in the food when considered in relation to the total diet so long as they do not include substances of known adverse biological activity e.g. heavy metals, pesticides, synergists, allergens and known carcinogens. These exclusions do, of course, significantly affect the generality of the proposition. Carcinogenicity is a special problem because here the concept of dose-dependence (i.e. that toxicity depends on how much is eaten) is being seriously questioned. In theory, no migration however small in amount should be permitted in repeated doses over long periods unless it has been shown by experiment not to be carcinogenic to animals. No such guarantee is possible for every potential or actual migrant and even if resources were available it would be a very long time before such tests could be carried out. However, it will be possible with the advice of the Pharmacology Sub-Committee to keep the problem under review. Meanwhile, we propose that only approved substances should be placed on permitted lists and this would enable the substances known or believed to be hazardous to be excluded. We consider that, unless there are good reasons to provide otherwise, all the ingredients should be tested for short-term toxicity unless, under the appropriate tests using food simulating solvents, they give negative results, i.e. they can be considered as not migrating.

A RECOMMENDED SYSTEM OF CONTROL

45. Although the nature of the problem is similar irrespective of the type of packaging material the scale of the problem is greatest with plastics. We think that, in principle, the same system of control should apply *mutatis mutandis* to all packaging materials.

Use of specifications

46. For lacquered metal cans—from which the risk on present evidence appears negligible—glass, ceramics and paper products it may well be practicable to base control on approved specifications. Much would depend on the number and variety of specifications which the industry required. We would, however, be prepared to consider representations from the organisations representing those industries for quantitive and qualitive specifications for packaging materials which are used in direct contact with food which is ready for immediate consumption such as cereals, drinks, etc. Specifications for these groups of packaging materials could then be approved by regulations and it would follow that any package not of an approved specification could not legally be used for the specified food purposes.

Total migration limit

47. Where there were no statutory specifications, we would propose to set a total migration limit for each type of packaging material and for each type of plastic, as appropriate. Although there are some objections in principle to this sort of limit e.g. it cannot be said to have any direct toxicological basis, we think that an appropriately chosen limit can act as a "long-stop" by setting an upper limit to the amount of extraneous substances that are allowed into the food. Since it is generally accepted that in this field nothing can be proved to be "safe", such a limit would reduce any risk to the consumer and would act as a stimulus to industry to use ingredients that remained in the packaging material. *We recommend* that industry should be invited to put forward specific proposals for such limits based on the use of the solvents and systems in Appendix II.

Substances to be included in a permitted list of ingredients

48. For the reasons set out in paragraph 38 *et seq*, we consider that any statutory

control should be by a permitted list of ingredients of packaging materials. This list should embrace all components of the packaging materials including monomers in the case of plastics and not simply the additives or adjuncts. The list should be based to the maximum extent on evidence of migration and toxicity and substances should be placed on the lists after scrutiny by the Food Additives and Contaminants Committee and the Pharmacology Sub-Committee as appropriate. We envisage recommending two categories of permitted ingredients for each main type of packaging materials (e.g. paper, waterproofed or treated board, transparent celluloses, polyvinylchloride (PVC), polystyrene and laminates). Category A would be substances of known toxicity and known extractability; Category B would contain other substances which would be included on a temporary basis and be subject to review at specified intervals or, exceptionally, whenever further information became available. We recognise that there should be frequent, e.g. annual, amendments to the lists and complete reviews at regular intervals e.g. five years. The list of permitted ingredients will be very long; although Category A will be relatively small. The total number of ingredients used in the packaging industry will, we expect, run to four figures.

49. *We recommend* that representative bodies of the packaging industry should therefore be invited to submit applications for substances to be included in the permitted lists. Wherever possible, the application should give full details of the proposed use of the substance and of its toxicity and all available information about migration. Although we should prefer information about migration to be based on the system of solvents proposed in Appendix II, we would be prepared to consider information of the results of other broadly comparable systems e.g. those used in other countries. We would also be prepared to include on a temporary basis in appropriate cases substances which were used in very small amounts i.e. 0.2% in the packaging, or which migrated in very small amounts, i.e. 0.01 mg per 100 sq. cm. Such substances might be included even if there was insufficient toxicity data but substances considered to be biologically active, e.g. heavy metals, pesticides, allergens, carcinogens and synergists, would have to be specially considered. Substances already included in the permitted lists of other countries would also be eligible for inclusion on a temporary basis. We should need to be given all available information on such substances as we would not wish, other than in exceptional cases, to include them without scrutiny and because certain conditions may well have been laid down when the approval was given.

50. We think it appropriate that the Category B list should in principle be restricted to substances already in use and that, as from a date to be specified, new substances would be required to fulfil the requirements for Category A. There should also be a progressive reduction in the number of substances in Category B over a suitably long period e.g. fifteen years under which substances on the Category B list would be required to comply with Category A requirements by a certain time or would be removed. We consider that substances used or migrating in small amounts could usually be given low priority for toxicity testing i.e. that they could be given a longer period before review than other substances.

51. A system of permitted lists of ingredients will only work if both the packaging and the food industry co-operate fully. It will be essential that ingredients and packaging materials should only be used in the manner intended; makers and users will need to know when special conditions apply. It would be necessary therefore for packaging materials to be registered by use and by list of ingredients. It would not be practicable for every small package to be so designated but it should be the duty of the manufacturer and the formulator of the package to make the requisite information available either on the batch material or in the accompanying documents. We should like to see registration of the various pack-

aging formulations and their uses by the appropriate industrial organisations.

52. When drawing up the lists we think it would be necessary to pay particular attention to substances which are subject to control by the food additives regulations. Some ingredients or potential ingredients will be on statutory permitted lists for food additives while others will have been deliberately excluded. We could not, for obvious reasons give any undertaking to accept as a general principle that the control of food additives should be vitiated by the migration of ingredients of packaging material; for example, it would be wrong if an antioxidant which under the Antioxidants in Food Regulations was not allowed in food at all, or which was allowed only in certain foods up to a specified maximum amount was, as a matter of course, to be permitted to migrate into any food even in small amounts and even if the extent of migration was limited by a total migration limit. We recognise that there might be good reasons to make exceptions e.g. for technically vital ingredients of known toxicity. We would be prepared to consider each case on its merits.

53. The system of food simulating solvents in Appendix II was drawn up in the light of comments from interested parties. *We recommend* that these solvents should be used as the basis of investigation and control although as mentioned in paragraph 49 we are prepared as an interim measure to accept the results of other systems. We do not regard the proposed system as the last word on the subject and we would be prepared to consider modifications especially in the light of experience.

54. We recognise that enforcement of the proposed system of control would not be easy. It would be possible to control by analysis the total migration limit and any limits for specified ingredients. Non-permitted ingredients could also be controlled to some extent by analysis. *We recommend* however that it should be made an offence to include a substance other than a permitted substance as an ingredient of a packaging material used or intended to be used for wrapping food. Local authorities would then be able by virtue of their powers under the Food and Drugs Act 1955 to enforce control by inspection in the factory. They would also be able to rely on information made available by manufacturers and formulators as envisaged in paragraph 51. Imported packaging material would have to be made the responsibility of the importer who would, we expect, be willing to provide the necessary information.

SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

55. (i) Much more factual information about the nature and extent of migration should be obtained in order to assess the extent of risk to the consumer (paragraphs 20 and 30).

(ii) It is neither prudent nor realistic to consider a system based on testing all ingredients of packaging materials (paragraph 30).

(iii) A system of food simulating solvents is recommended for the purposes of investigation and control (paragraph 36 and Appendix II).

(iv) Criteria for assessing safety-in-use can be relaxed but risks and benefits can only be fully assessed when the actual substances which might have to be included in a permitted list are known (paragraphs 43 and 44).

(v) Dr. Frawley's proposal provides a useful practical basis for action (paragraph 44 and Appendix III).

(vi) The same system of control should apply *mutatis mutandis* to all packaging materials (paragraph 45).

(vii) A total migration limit for each type of packaging material and plastic, as appropriate, should be laid down based on the use of the recommended solvents. Industry should be invited to put forward specific proposals (paragraph 47).

(viii) Control should be by permitted list of ingredients embracing all components of packaging materials including monomers and it should be based to the maximum extent on evidence of migration and toxicity (paragraph 48).

(ix) Two categories of permitted ingredients are envisaged for each main type of packaging material. Category A would be substances of known toxicity and known extractability; Category B would be other substances included on a temporary basis (paragraph 48).

(x) Representative bodies of the packaging industry should be invited to submit applications with full details of the proposed use of the substance and its toxicity and all available information on migration (paragraphs 49 and 53).

(xi) Consideration would be given to including in Category B substances permitted elsewhere and those used or migrating in small amounts (paragraph 49), but the Category B substances ought to be progressively reduced over a suitable period (paragraph 50).

(xii) It would not be right as a general principle that migration of food additives controlled by regulations should be allowed automatically but there might be good reasons to make exceptions (paragraph 52).

(xiii) It should be made an offence to include a substance other than a permitted substance in a packaging material used or intended to be used for wrapping food (paragraph 54).

LIST OF ORGANISATIONS AND INDIVIDUALS FROM WHOM EVIDENCE HAS BEEN RECEIVED

Adhesive Manufacturers' Association
Albright and Wilson Ltd.
Association of Public Analysts
Bakelite Xylonite Ltd.
Bowmans Chemicals Ltd.
B.P. Chemicals (U.K.) Ltd.
British Aluminium Foil Rollers Association
British Carton Association
British Colour Makers' Association
British Food Manufacturing Industries Research Association
* British Industrial Biological Research Association
British Nutrition Foundation Ltd.
British Paper and Board Makers' Association Incorporated
* British Plastics Federation
British Resin Products Ltd.
British Sidac Ltd.
British Standards Institution
Ciba Clayton Ltd.
Commercial Plastics Ltd.
County Councils Association
Croda Ltd.
Danish Embassy
Dickinson Robinson Group Ltd.
Dr. Bernard Dyer and Partners (1948) Ltd.
Dunlop Rubber Co. Ltd.
Du Pont Company
The Flexible Packaging Association
The Food Manufacturers' Federation Incorporated
* Dr. J. P. Frawley and Dr. J. C. Higgins
W. R. Grace Ltd.
Hercules Powder Company Ltd.
Honeywill-Atlas Ltd.
Imperial Chemical Industries Ltd.
Informal Toxicity Committee of Vinyl Sheet Manufacturers
Institute of Packaging
Institute of Weights and Measures Administration
Keller and Heckman, U.S.A.
Marbon Chemical
Marks and Spencer Ltd.
The Metal Box Company Ltd.
Milk Marketing Board
Mobil Oil Company Ltd.
Nipa Laboratories Ltd.
Packaging Films Manufacturers Association
Parliamentary Committee (Co-operative Union Ltd.)
Pure Chemicals Ltd.
* Reed Paper Group

* Gave oral evidence.

The Research Association for the Paper and Board, Printing and Packaging Industries
Shell International Chemical Co. Ltd.
Smith and Nephew Research Ltd.
Society of British Printing Ink Manufacturers
Star Aluminium Company Ltd.
Transparent Cellulose Wrappings Committee
Vinyl Products Ltd.
Viskase Ltd.

* Gave oral evidence.

Leaching of Substances from Packaging Materials into Food 'Food-Simulating' Solvents

1. A procedure for using solvents for investigating the extent of migration and for purposes of control is referred to in paragraphs 34 to 36, 47, 49, and 53 of the Report.

2. The recommended solvents, together with the appropriate contact times and temperatures are shown in the following table, which also shows the nature of the packaged food to which each system is appropriate:

Nature of Packaged Food	Recommended Solvent System	Contact Time and Temperature
Neutral	Water	37°C for 48 hours
Acidic	3 per cent, Acetic acid	37°C for 48 hours
Alcoholic	10 per cent, Ethanol	37°C for 48 hours
Lipid	50 per cent, Ethanol	37°C for 48 hours

3. It is recommended that an area equivalent to 1,000 sq. cm. of the packaging materials, in pieces of not more than 100 sq. cm. be held at the recommended temperature (± 0.5 °C) for the specified time with continuous stirring, in a volume of 500 ml. solvent.

4. Solvent removal from the resultant extract (which should be filtered through a medium of porosity appropriate to the physical character of the extracted packaging material) should be effected under reduced pressure, at a temperature not exceeding 60°C, and in an atmosphere of nitrogen. The solvent recovery vessel should be equipped with a suitable anti-splash device where necessary

5. The extract, after removal of the solvent, should be dried to constant weight in a desiccator at room temperature, and weighed to the nearest milligram.

6. The weight of the extract obtained from an area of packaging material equivalent to 1,000 sq. cm., should be reported to the nearest milligram.

[All the areas given above refer to one side of the packaging material. For a non-laminate, solvent extraction by the procedure above results in the contact of *both sides* of the 1,000 sq. cm. sample of packaging material with the solvent. Ignoring the edges (which may be regarded as of insignificant area in comparison with the sides) *the total* area extracted is thus 2,000 sq. cm.]

THE FRAWLEY PROPOSAL[1]

1. Dr. J. P. Frawley, Chief Toxicologist, Hercules Inc. was concerned about the complexity of the system controlling the use of packaging materials under the Food and Drugs Administration U.S.A. In an effort to simplify the complex maze of regulatory procedures he suggested that it was safe to assume that 0.1 ppm in the human diet would be safe for any chemical which would be a technically suitable component of a food container.

2. Dr. Frawley tabulated the "no-effect" levels from every two-year (long-term) toxicity study which he could find (220 in all)—without selection or rejection except irradiated foods. From this tabulation he noted that the majority of chemicals were non-toxic to experimental animals even at dietary levels of 100 ppm; and that, except for pesticides and heavy metals, none were toxic at levels below 10 ppm. Dr. Frawley then applied the conventional 100-fold margin of safety to these experimentally determined "no-effect" levels and concluded that, even without toxicity studies, it would be safe to assume that dietary levels of 0.1 ppm. or less would not present a hazard to human health, except for pesticides and heavy metals.

3. Dr. Frawley then reviewed the results of studies on the migration into various foods of rosin size from paper and paper-board. This he considered represented the most extreme case of migration from a packaging material and should therefore represent a maximum for any component of any packaging formulation. From these results he calculated that a level of 0.2 per cent rosin size in the paper or paper-board would contribute no more than 0.1 ppm of rosin size to the diet —assuming that no more than 25 per cent of man's diet was in contact with any given type of food packaging material.

4. Dr. Frawley concluded from the above that any component of any article contacting food which is present in the article itself or its coating at a level of 0.2 per cent or less by weight—excluding pesticides and heavy metals—will contribute to the diet a level which can be of no possible public health significance.

[1] Scientific Evidence and Common Sense as a Basis for Food-Packaging Regulations J. P. Frawley. *Fd. Cosmet. Toxicol.*, 1967, *5*, 293-308.

A note on the main ingredients of plastic packaging materials

1. Plastic packaging material is formulated according to the use for which it is recommended. As used for foods, it contains (a) the basic polymer of high molecular weight and chemically inert, (b) traces of monomer, (c) residues of processing aids such as catalysts and surface active agents and (d) additives such as antioxidants, plasticisers, stabilisers required for the conversion of the polymer into the final container or wrapping.

2. It is appropriate to describe the main packaging materials according to their basic polymer viz: polyvinylchloride, polyolefins or polystyrene.
3. Polyvinylchloride (P.V.C.) for food use is supplied as (a) rigid P.V.C., (b) flexible P.V.C.

(a) Rigid P.V.C. is used as thin sheet and for containers such as bottles. It contains ultra-violet stabilisers, which include calcium and zinc salts of fatty acids, 2-phenylindole and certain organotin (dioctyl) compounds of very low trialkyltin content; lubricants such as fatty acids and fatty alcohols; and impact modifiers which are polymeric materials such as butadiene acrylonitrile copolymers.

(b) Flexible P.V.C. contains plasticisers, often in large amount but restricted to specific esters, phthalic acid and monobasic and dibasic fatty acids; and ultra-violet stabilisers similar to those in rigid P.V.C. Flexible P.V.C. is not recommended for uses when the plasticiser can migrate into the food to its detriment.

4. Polyolefins, i.e. polyethylene and polypropylene, contain insignificant traces of monomer and polymerisation residues such as alkaline earth metal oxides. The usual additives are antioxidants such as butylated hydroxytoluene and some other antioxidants which are not on the permitted list of antioxidants for food; lubricant e.g. fatty acids; antistatic agents ,e.g. fatty amides (at about 0.1% level) and ultra-violet absorbers which are usually substituted benzophenones or substituted phenols. No ultra-violet stabilisers or plasticisers are used.

5. Polystyrene. A merest trace of monomer would affect the flavour of foodstuffs, so great care is taken by manufacturers to ensure that the monomer content is negligible. Some polystyrene for foodstuffs is 'impact improved' by the addition of about 5% of rubber-type compounds. The polymer will contain small amounts of polymerisation residues of catalysts such as organic peroxides and emulsifiers and suspending agents such as alkyl aryl sulphonates, and among processing aids there are stabilisers, such as sodium phosphate, lubricants such as fatty acids and fatty alcohols and certain antioxidants which are not on the permitted list of antioxidants for food.

Printed in England for Her Majesty's Stationery Office, by Elliott Bros. & Yeoman Ltd., Liverpool
4069 Dd. 147048 3000 3/70 Gp 474